

SEP - 6 2005

**510(k) Summary  
for  
Sirona Dental Systems  
Implant Handpieces**

**1. SPONSOR**

Sirona Dental Systems GmbH  
Farbrikstrasse 31  
64625 Bensheim  
Germany

Contact Person: Fritz Kolle  
Regulatory Manager

Date Prepared: August 26, 2005

**2. DEVICE NAME**

Proprietary Name: Implant Handpieces  
Common/Usual Name: Dental Handpiece  
Classification Name: Dental Handpiece

**3. PREDICATE DEVICES**

W & H WS-75 E/KM Handpieces (K011061)

**4. INTENDED USE**

The Sirona Dental Systems Implant Handpieces are intended for use during endodontic treatment, dental implant surgeries and general dentistry. The Sirona Implant 20:1/80:1 Contra-angle handpieces are indicated for surgery, implantology and general dental applications (drilling, grinding etc.).

**5. DEVICE DESCRIPTION**

The Sirona Implant Handpieces are handpieces with transmission ratios of 80:1 and 20:1. They can be driven by torque adjustable electrical motors for surgery treatments and air motors for general dental treatment. The Implant handpieces are attached to their drives via ISO 3964 coupling. A saline irrigation system for surgery treatment is integral to the Implant Handpieces. The head clamp accepts WB instruments complying with ISO 1797-1.

**6. BASIS FOR SUBSTANTIAL EQUIVALENCE**

The overall design of the Sirona Implant Handpieces is similar to the design of the W & H WS-75 E/KM handpiece in that all of these devices allow the use of instruments complying with ISO 1797-1, the connection to motor via the standardized ISO 3964 coupling and offer a similar saline irrigation system.

Based on the comparison of intended use and technical features, Sirona Dental Systems believes that the Sirona Implant Handpieces are substantially equivalent to the predicate W & H Handpiece. The proposed and predicate devices have the same general intended use and principles of operation. The overall design of the proposed and predicate devices is similar.



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

SEP - 6 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Sirona Dental Systems GMBH  
C/O Mary McNamara-Cullinane  
Medical Device Consultants, Incorporated  
49 Plain St.  
North Attleboro, Massachusetts 02760-4153

Re: K051661  
Trade/Device Name: Implant Handpieces  
Regulation Number: 21 CFR 872.4200  
Regulation Name: Dental handpiece and accessories  
Regulatory Class: I  
Product Code: EKX  
Dated: June 21, 2005  
Received: June 22, 2005

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices,  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K051661

Device Name: Sirona Dental Systems Implant Handpieces

**Indications for Use:**

The Sirona Implant 20:1/80:1 Contra-angle handpieces are indicated for surgery, implantology and general dental applications (drilling, grinding etc.).

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use         
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number:   K051661  

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Sirona Dental Systems  
Additional Information – K051661

August 26, 2005